

EVALUATION OF INITIAL FLUID RESUSCITATION TO IMPROVE OUTCOME IN INFANTS AND CHILDREN WITH HYPOXIC CARDIAC ARREST

Investigators

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Neurologic injury after out-of-hospital cardiac arrest is common, accounts for much long-term neurologic morbidity, and appears to directly correlate with the duration of cardiac arrest and cerebral ischemia. To date there have been no studies designed to evaluate the poor outcomes associated with out-of-hospital cardiac arrest in pediatric populations. Previous research has shown that much of the neurologic injury during hypoxic arrest occurs secondary to oxygen radical formation. Additionally, albumin has been demonstrated to sequester oxygen radicals, thereby conferring protection against their damaging effects. The proposed study will use albumin during the resuscitation of pediatric patients who have suffered an out-of-hospital cardiac arrest to determine whether this fluid strategy will improve survival and long-term neurologic outcome.

OBJECTIVE

To determine whether the use of albumin during the resuscitation of pediatric patients who have suffered an out-of-hospital cardiac arrest reduces the severity of acute hypoxic-ischemic injury.

STUDY DESIGN

A. Patient Population

Pediatric (birth to 15 years of age) patients in cardiac arrest.

B. Inclusion Criteria

Patients who require cardiopulmonary resuscitation (CPR) for cardiac or respiratory arrest will be considered eligible for the study. An arrest will be defined as the initiation of CPR by either bystanders or prehospital

Personnel. Patients will be eligible for the study regardless of the etiology of arrest (i.e. drowning, arrhythmia, and respiratory arrest).

C. Exclusion Criteria

Purpura fulminans (Septic Shock)

D. Study Design

Randomized controlled interventional trial. A power analysis will be performed when 20 patients have been enrolled (10 in each arm) to determine how long the study would need to continue if any trends were noted.

E. Protocol

Patients will be randomized to one of two groups:

Group 1/Even days – ALS prehospital personnel will follow approved ICEMA protocols. (See Attached) Protocol Reference #7000 Pediatric Cardiac Arrest (1Day to 8 years of Age) and Protocol Reference #7002 Pediatric Cardiac Arrest (9 to 15 years of Age)

Group 2/Odd days – ALS prehospital personnel will follow the study protocols. Protocol Reference #7000TS Pediatric Cardiac Arrest (1Day to 8 years of Age) and Protocol Reference #7002TS Pediatric Cardiac Arrest (9 to 15 years of Age)

Patients on odd days will receive a 20cc/kg initial bolus of 5% Albumin in place of Normal Saline. If the patient has a return of any perfusing rhythm they will receive an additional bolus of 20cc/kg of albumin. Otherwise, the protocols will remain identical.

F. Training

There will be an initial Train the Trainer Session taught by an Investigating Physician from materials developed by this physician. The individuals selected for the Train the Trainer Session shall at a minimum fulfill the following criteria:

1. Approved by the Investigators
2. RN or Physician Assistant with demonstrated teaching skills
3. Knowledge of ICEMA Protocols & Procedures

All EMT-Ps within ICEMA whose agencies will participate in this study will receive five (5) hours of training. This training will consist of a structured educational presentation. The topics covered in the presentation will include the following:

1. Background information about the study rationale.
 - a. Literature review of pediatric cardiac arrest.
 - b. Current approaches to pediatric cardiac arrest.
 - c. Current outcomes of pediatric cardiac arrest.
2. Literature review of fluid resuscitation.
 - a. Comparison of normal saline and albumin.
 - b. Review of the literature involving the use of albumin.
 - c. Protective mechanisms of albumin.
3. Protocol outline.
4. Integration with existing protocols and procedures.
5. Outline of mechanisms available for feedback and follow-up.
6. Questions.